12. DATA MANAGEMENT

MDS Pharma Services Standard Operating Procedures (SOPs) will be adhered to for all activities relevant to the quality of the study.

All clinical data will undergo a 100% quality control check prior to clinical database lock. Edit checks are then performed as a validation routine using SAS to check for missing data, data inconsistencies, data ranges etc. Corrections are made prior to statistical database lock.

Case Report Forms are printed off directly from the database. Each CRF is reviewed and signed by the Principal Investigator. A hard copy of the plain CRFs will be sent to the Sponsor.

A data management plan will be prepared by MDS and provided to the Sponsor for review. Upon completion of the study, the database will be transferred to the Sponsor in SAS format.

Source: https://www.industrydocuments.ucsf.edu/docs/jfnj0001